NOV - 7 2005

K052638

Abbott Spine, Inc.
Spinnaker System

510(k) Summary of Safety and Effectiveness

SUBMITTED BY	Abbott Spine, Inc. 5301 Riata Park Court, Bldg. F Austin, TX 78727
ESTABLISHMENT REGISTRATION NUMBER	1649384
CONTACT PERSON	Lisa Peterson Regulatory Affairs Manager Phone: 512-533-1080 Fax: 512-249-6734
DATE PREPARED	September 19, 2005
CLASSIFICATION NAME	KNW 876.1075- Gastroenterology-Urology Biopsy Instrument: Class II KIH 888.4200- Cement Dispenser: Class I
COMMON NAME	Vertebral Body Biopsy Needle Cement Dispenser
PROPRIETARY NAME	Abbott Spine Inc. Spinnaker System
SUBSTANTIAL EQUIVALENCE	The Abbott Spine Spinnaker System was determined to be substantially equivalent to the Stryker Capture Vertebral Body and Bone Biopsy Kit and the Parallax Medical Core-Assure Bone and Vertebral Body Biopsy Kit.

DEVICE DESCRIPTION:

The Abbott Spine, Inc. Spinnaker System is intended for use as a vertebral body biopsy and cement dispenser device. The system is comprised of aspiration/injection taps, handles, a targeting needle, a bone awl, ports and dilators, a Luer cap, and k-wire. The system provides the surgeon with a convenient method of performing vertebral body bone biopsy, as well as dispensing cement cleared for use in the spine into a vertebral body using a single system.

INDICATIONS:
The Abbott Spine Spinnaker System is intended for use as a stand alone biopsy tool to remove a sample of bone tissue from a vertebral body for diagnostic purposes using an aspiration technique, as well as to provide and maintain access to the same surgical site.

When used as a cement dispenser, the Spinnaker System is intended to dispense cement cleared for use in the spine into a vertebral body for vertebral body augmentation using a vertebroplasty procedure.

MECHANICAL TEST DATA
Mechanical testing demonstrated that the Spinnaker System exhibits the functional requirements to support its use for performing vertebral body bone biopsy and dispensing cement into a vertebral body for vertebral body augmentation.

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Austin, Texas 78727
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 2005

Lisa Peterson
Abbott Spine, Inc.
Regulatory Affairs Manager
5301 Riata Park Court, Building F
Austin, Texas 78727

Re: K052638
Trade/Device Name: Spinnaker System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW, KIH
Dated: September 19, 2005
Received: September 27, 2005

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K052638

Device Name: Abbott Spine, Inc. **Spinnaker System**

Indications for Use:

The Abbott Spine Spinnaker System is intended for use as a stand alone biopsy tool to remove a sample of bone tissue from a vertebral body for diagnostic purposes using an aspiration technique, as well as to provide and maintain access to the same surgical site.

When used as a cement dispenser, the Spinnaker System is intended to dispense cement cleared for use in the spine into a vertebral body for vertebral body augmentation using a vertebroplasty procedure.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052638